



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-2873]

### Voluntary Malfunction Summary Reporting Program for Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.” We are publishing this notice of availability for this draft guidance document to help manufacturers better understand and use the VMSR Program. It is intended to further explain, but not change, the conditions of the VMSR Program. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2022-D-2873 for "Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Michelle Rios, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.

1116, Silver Spring, MD 20993-0002, 301-796-6107 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

Each year, FDA receives over 2 million medical device reports (MDRs) of suspected device-related deaths, serious injuries, and malfunctions. The MDR Program is one of the postmarket surveillance tools that FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Malfunction reports represent most of the MDRs received by FDA on an annual basis. As part of FDA's postmarket surveillance for devices, the Agency reviews the MDRs submitted by both mandatory and voluntary reporters.

The VMSR Program (the Program) began in 2018 when FDA issued a notification in the *Federal Register* of August 17, 2018 (83 FR 40973) of an order granting an alternative under 21 CFR 803.19 that permits manufacturers of devices in eligible product codes to report certain device malfunction MDRs in summary form on a quarterly basis, subject to the conditions of the alternative. The Program is intended to streamline reporting for device malfunctions as outlined in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter. As such, it is intended to yield benefits for FDA, the public, and manufacturers, such as increasing transparency for the public, helping FDA to process certain malfunction reports more efficiently, allowing both FDA and the public to identify malfunction trends more readily, and reducing the burden on manufacturers. FDA implemented the Program only after the Agency had conducted a pilot program<sup>1</sup> that demonstrated the value of a program for summary medical device reporting on malfunctions to public health, better use of Agency resources, and promotion of public transparency.

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<sup>1</sup> See Pilot Program for Medical Device Reporting on Malfunctions, 80 FR 50010.

This draft guidance describes and clarifies several aspects of the Program. The draft guidance includes information on FDA’s approach to determining the eligibility of product codes for the Program and the conditions for submitting MDRs for device malfunctions in summary format under the Program. The draft guidance also includes information on how manufacturers may submit information in the summary reporting format, including instructions on how to complete applicable sections of Form FDA 3500A.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 21007 and complete title to identify the guidance you are requesting.

### III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting	0910-0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Dated: December 5, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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